TELANGANA LEGISLATIVE COUNCIL
SESSION: 1

L.C.Q. No. (Starred) 11

Notice given by :
Sri Ponguleti Sudhakara Reddy, MLC

Will the Deputy Chief Minister (Medical & Health) be pleased to state:

a) Whether it is a fact that several Pharmaceutical Companies are conducting clinical trails on the poor tribals of agency and backward areas in the State ;

b) Whether it is also a fact that the Drug Control General of India has stipulated guidelines in this regard and the details thereof ; and

c) The number of cases registered till now and the action taken thereon?

HEALTH, MEDICAL & FAMILY WELFARE (C2) DEPARTMENT

ANSWER

a) Yes Sir.

b) Yes Sir.

c) There are 3 cases pending in State Human Rights Commission (SHRC) for disposal.

(The above answer has been approved by the Hon'ble Deputy Chief Minister (Health, Medical & Family Welfare))

for PRINCIPAL SECRETAY TO GOVERNMENT

To
The Secretary, Telangana State Legislative Council (Questions) Dept.,
Council Buildings, Hyderabad.
Copy to: -
The P.S. to Spl. Secretary to C.M.
The OSD to Dy.C.M(Medical & Health)
The General Administration (L&C)T.S., Dept.
The P.S. to Prl. Secy., to Govt., HM&FW Dept.
HM & FW (F) Dept.
Sf/Sc.

U.O. Note No.1602/C2/2014, HM & FW (C2) Dept., Dated: 20-09-2014

NOTE FOR SUPPLEMENTARIES TO LCQ NO. 11 (STARRED) GIVEN NOTICE BY SRI PONGULETI SUDHAKARA REDDY, MLC

1. The clinical trails in India are regulated under the Drugs and Cosmetics Act 1940 and Rules 1945 there under. Clinical trails are defined under Rule 122 DAA under part X-A of the Drugs and Cosmetics Rules, 1945 as a systematic study of new drug (s) in human subjects(s) to generate data for discovering and / or verifying the clinical, pharmacological (including pharmacodynamic and Pharmacokinetic) and / or adverse effects with the objective of determining safety and / or efficacy of the new drug.

2. The drugs Controller General of India, New Delhi is the Licensing Authority appointed by the Central Government under clause (b) of Rule 21 of Drugs and Cosmetics Rules, 1945, who is the Head of Central Drugs Standard Control Organization (CDSCO) under the Government of India and is also the sole authority who grants permission for the conduct of clinical trails throughout the Country.

3. Guidelines are stipulated by Drugs Controller General of India, New Delhi under schedule "Y" of Drugs and Cosmetics Rules, 1945 and Good Laboratory Practices (GLP) guidelines, for conducting clinical trials.

4. Telangana State Drugs Control Administration has no role in processing the applications of these organizations for approval of clinical trails and regulating the day to day activities of these organization as per the Drugs and Cosmetics Act, 1940 and Rules 1945.

SURESH CHANDA
PRINCIPAL SECRETARY TO GOVERNMENT